



**National Institute for
Health Research**

**Clinical Research Network
Coordinating Centre**

The Way Forward

Making a difference in research by actively involving people:

The Report



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Preface

The National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) has undertaken an extensive consultation process called The Way Forward for actively involving people with research. This has clearly demonstrated that we are now entering a new phase in the development of involving people across the Networks where there is a need for greater coordination, cooperation and clarity of purpose.

The Way Forward has drawn strength, knowledge and clarity from a process of collaborative engagement and participation in its aim of producing a report to form the basis of a business plan for the Department of Health to make a difference in research by involving people. The Way Forward Panel were extremely impressed with the increasing coherence around the purpose of involving patients, carers and the public across the National Institute for Health Research Clinical Research Network (NIHR CRN). Exceptional innovative examples were provided of the breadth and quality of such involvement.

The value and importance of involving people who are not traditionally part of the health research community was clearly being acknowledged and recognised. Yet concerns were expressed around certain pockets of tokenism and some of the inappropriateness of such involvement e.g. putting someone on a committee for the sake of ticking a box.

Network Directors were pleased to be given the opportunity to help shape this area of work and showed strong commitment and support rather than feeling that they were being told to do it. A key strand of these particular discussions was that the underpinning argument of involving people is won, that research would be less effective without the focus provided by these voices and contributions. This re-focuses our purpose to improve research.

The Patient and Public Involvement (PPI) Leads are showing effective leadership in creating and developing this work in an innovative and exciting manner. The Panel commented on the strength of this leadership positively.

There has been a significant shift away from the parameters of 'them and us' towards a more complex yet more productive dialogue where research professionals are more willing to join with patients and carers to develop new and improved approaches to health issues. At the same time, patients, and carers are increasingly focused and knowledgeable in their role with professionals in this regard.

Increasingly there has been a desire to develop more consistent and coherent approaches to ensure resources are well spent. This will help channel the enthusiasm and commitment of patients, carers and the public in their involvement to better effect across the entire Network.

This report is aligned very closely with the recent NHS White Paper and NIHR Annual Report both of which provide strong credence to the placing of patient benefit at the centre of all our work. The Big Society has been an integral part of research for over ten years.



Derek C Stewart, OBE

Chair of The Way Forward Panel

1. Introduction

The report is not the conclusion of this process we have called the Way Forward. It is intended to act as a milestone along the path of transition between a period when the involvement of patients and carers was being established, interpreted and developed in the NIHR Clinical Research Network (NIHR CRN) to the next phase.

This is the opportunity to build on the experience and achievements of the last five years or more, moving to the phase where the involvement of patients, carers and the public becomes more focused on improving research and its delivery, and leads to impacts that relate directly to Network responsibilities for delivering research relevant to NHS patients quickly and effectively. Ultimately these dialogues were about improving research for the benefit of NHS patients.

The dialogues were hosted by a Panel of people from both inside and outside the NIHR CRN. Initially the Panel met with a wide range of people involved in the Networks at different levels, as well as other stakeholders. This was followed by a consultation consisting of a web based survey and a one day workshop event in Leeds. Separate meetings took place with Network Directorates. There have been numerous other side dialogues too in regular groups such as the NIHR CRN's own PPI Working group, PPI Forum, and the Operational Steering Group. These have fed into the process and helped develop thinking. Overall people have been enthusiastic to work in this way.

Much of the document covers strategic issues, which specifically affect the involvement of people in the Networks. Some of the content has external implications, but much of it concerns the orientation of PPI in the Network context. The report therefore assumes prior knowledge of the Networks, their purpose and primary objectives and knowledge of involving patients, carers and public in general.

The report focuses on the conclusions and recommendations of The Way Forward Panel. There is also a greater wealth of background, which emerged as part of the process which is not reported here and is being collected in a further document.

The dialogues have been central to a development process that has been a valuable 'in the moment' evolution of PPI thinking and practice. The report is therefore a milestone in that process, a record of the journey so far and a platform for continued development work.

It is our intention, in future documents, to encourage people to contribute examples of good practice and impact, attributed to individuals and Networks as a tangible celebration of the excellence that is taking place in involving patients and or carers and the public in improving research.

The Way Forward has been developed in the context of maximising coordination and coherence in PPI across the whole of NIHR CRN. This is particularly timely now that all of the Network is established. The recommendations arising from this work will inform the priorities which will drive the development of the NIHR CRN PPI strategy and associated programme of work for the next five years. To consolidate this, the CRN Coordinating Centre has been tasked with developing a business plan to support delivery of these activities. This

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must consider best use of available resources in terms of maximising the impact of PPI in supporting NIHR CRN delivery. The business plan will be submitted to the Department of Health for approval by 31st March 2011 and, once approved, will be followed by further work, undertaken collaboratively across NIHR CRN, to implement these plans. The activities, issues and recommendations included in this report will be central in supporting the development of this important programme of work. Once established, it will inform the successful delivery and ongoing development of PPI across the NIHR CRN over coming years.

2. Summary of Recommendations

The *Way Forward* is a coordinated plan for patient, carer and public involvement (PPI) in the NIHR Clinical Research Networks. The plan will ensure that the patient's voice and opinion is at the heart of the functioning across the Networks. This document outlines the case, the ambition, and the practical plan to enable involvement to make a difference.

1. Background

First that patients must be at the heart of everything we do, not just as beneficiaries of care but as participants in shared decision making. As patients, there should be no decision about us without us.

Andrew Lansley, CBE, MP – Secretary of State for Health

High quality research matters and is of interest to patients, carers and the public especially when it is relevant to and addresses patient needs. Patients want information about research and are keen to take part in trials to help improve their health and well-being.

The involvement of patients, carers and the public in research needs to continue to be an embedded culture that places the patient at the centre of the work of the National Institute for Health Research Clinical Research Network (NIHR CRN). This involvement is based on the premise that involvement is ethical, enhances research, demonstrates the openness of research, improves recruitment, and enriches the process.

This centrality was acknowledged by the Department of Health following its 2009 reviews of the NIHR CRN Coordinating Centre (CRN CC) and the Topic specific Clinical Research Networks (TCRNs). The Department of Health reviews highlighted the opportunity to achieve greater coordination and coherence for patients and public involvement across the Networks – providing an opportunity for shared practice, clear processes and coherent strategies. Consequently the NIHR CRN CC was commissioned to develop a plan for the future.

Patient, carer and public: Involvement in research

Insights are gained from patient and carer and public experiences.

There should be more explicit opportunities to become involved.

The opportunities should be more clearly explained in terms of trial design, delivery and dissemination.

The *Way Forward* process brought together a wide range of stakeholders to achieve the Department of Health requirements of increasing coordination and coherence for the involvement of patients, carers and the public across the whole of the NIHR CRN. Building on the achievements of the last five years, *The Way Forward* brought together a Panel comprising representatives from different stakeholder groups, both inside and outside the

Clinical Research Networks. The Panel helped to gather information from a wide range of contributors, in order to make recommendations to the Department of Health.

The Way Forward Panel recognised the diversity of approaches necessary across disparate networks – for example the National Cancer Research Network is recruiting into trials that are usually secondary care (hospital) based, while the Diabetes Clinical Research Network recruits largely from primary care (local clinics and GP practices). The Panel had also considered the whole-system pathway of a research study from design to completion and considered the potential patient, carer and public interventions in terms of their added value – ethical, pragmatic, social and cultural.

2. Process

The Panel recommendations are, necessarily, part of an evolving cooperative culture that will be central to the success of the involvement of patients, carers and the public across all the networks of the NIHR CRN.

The wide consultation and the processes of iterative feedback enabled us to formulate an overview of how we might approach a more coherent, collaborative and co-ordinated approach to PPI, while recognising the necessary specificity of the network approaches.

Greater coherence needs to be about clarity of purpose, language and action. Better collaboration ensures that we share and learn from each other. Improved coordination enables more effective value for money.

3. Implementation Plan

The following points emerging from the wide consultation, outline the necessary recommendations to achieve the step change to improve the impact of the involvement of patients, carers and the public:

- A. Identify and target activity in a commonly agreed framework
- B. Develop better cross-network and cross-NIHR collaboration
- C. Formalise evidence gathering and dissemination
- D. Integrate learning and development opportunities

Coherence

- **Promote** the involvement of patients in research studies
- **Encourage and sustain** such involvement – for reasons that are ethical, pragmatic, social and cultural
- **Target involvement** where it creates the maximum **benefit and impact**

Collaboration

- **Recognise, acknowledge and share** good practice
- **Gather patient experiences**, and use these as a stimulus for change
- **Create** a series of dialogues on issues that matter to patients

Coordination

- **Co-ordinate** activities, where possible, across the networks.
- **Ensure equity** whilst recognising **diversity** across the networks' activities

These four recommendations will be achieved through a framework agreed between the co-ordinating centre and the relevant networks.

A. Identify and target involvement by developing an agreed framework of activities

The intention is to focus activity where it is most effective. We will achieve this by developing a framework that identifies, targets and describes involvement activity.

Patient involvement has a clear impact on research. Quantifying the impact is challenging, but describing it is both possible and necessary. Emerging innovative approaches act as exemplars for further improvement of practice: carers' and patients' views add value; involvement demonstrates an open approach of researchers; patient involvement improves training of health care workers; patients can identify flaws in design and especially in recruitment strategies; patients can become part of the advocacy for recruitment into trials.

The framework will be aligned to NIHR objectives and provide a broad structure within which Networks set out their practice of involving patients, carers and the public without hampering individual approaches. It will also serve as a more coherent checklist for developing, monitoring and evaluating activity. This will promote innovation and creativity. The framework will be based on the issues listed in Section 5 on Page 17.

Recommendation: Develop, agree and implement a practical PPI working framework related to impact.

B. Develop better cross-network and cross-NIHR collaboration

The intention is to increase and further develop the well-established collaborative work that already exists between the networks and within the NHS and NIHR family.

B1 Network collaboration

PPI has been a core activity of the Topic Networks but the strength and focus can be maximised through working more collaboratively as a 'team'. Each Network has its own ethos and individual needs, yet the basic processes of involvement are fundamentally similar. Improved collaboration and sharing of expertise will strengthen and broaden the Network PPI teams whilst maintaining the individuality. Individual networks will be encouraged to lead on aspects of involvement, including reporting good practice and liaising widely to achieve a coordinated approach. Common and shared resources and activities will then become open to all Networks, and a central repository of resources, examples, good practices, and generic educational and trial-recruiting material will be established.

In PPI, the nature of leadership involves shared decision making, and is not only optimal for effective and open management but also embraces equality of opinion and recognition of status between health professionals and the public. This is as important in the routine doctor-patient relationship as it is with involvement in the research environment. The aim is to enhance the collaboration to the mutual benefit of patients and researchers alike.

One approach to leadership will be to find a sustainable model, which embraces opinions from a wide body of stakeholders. Collaboration will be the key to utilising expertise and perspective – and thus maintaining the focus of research on benefit and relevance to patient and carer wants and priorities

B2 External collaboration

Many external organisations can contribute to the patient and public involvement agenda, and we will liaise to embrace a wide variety of views and expertise. In the early stages of research design PPI can deliver improvements in many pragmatic aspects: recruitment strategies, patient information, maximising qualitative returns, formulating questionnaires, and planning public dissemination. Aspects relevant to patients can be embraced and the design and relevance to NHS patients can be maximised. Some topic Networks have set up panels to aid researchers at the earlier stages, and this should be encouraged. The culture must be that of involvement at every relevant stage of the process – and the benefits should be a further encouragement for those involved. On-going engagement with research funders and other organisations such as National Research Ethics Service (NRES) & INVOLVE, is needed to develop greater understanding and agreement about the value of strategic involvement of patients, carers and the public along the whole of the research pathway. Developing a relationship with Industry will also be key to making improvements as will cognisance of the activities in the devolved nations.

Recommendation: Strengthen collaborations through existing and new approaches through better coordination systems and structures in the Networks.

Recommendation: Foster and rationalise greater collaboration with other organisations in respect of involvement activity, which can impact on the success of the Networks and better quality studies.

C. Formalise evidence gathering and dissemination

There is a need to systematically gather evidence and examples, and share knowledge. Meaningful quantitative metrics are challenging to identify and many benefits in this field are difficult to measure, yet we know the achievement of recruitment targets can depend on successful PPI. However, qualitative examples show the impact of PPI on enhancing research, demonstrate the openness of the process, improve recruitment, and enhance the outcome. By gathering examples systematically we can not only demonstrate the outcomes of PPI activities, but also disseminate the examples to enhance learning and information throughout the networks.

Recommendation: Formalise the gathering of evidence and formulate a dissemination strategy

D. Integrate Learning and Development Opportunities

There is a need to establish a learning network enhanced by a small infrastructure and based on shared resources. This will be specifically related to the work of the Clinical Research Networks and provide patients and carers with opportunities to develop necessary skills and knowledge. Cascaded learning approaches will be utilised to widen access and promote innovative methods such as e-learning, self-directed learning, mentoring schemes, and action learning.

This will build on the work undertaken by the Training and Education Working Group in 2009. We will continue to work with INVOLVE and others to collate learning opportunities and improve practice.

Recommendation: Establish a learning network directed at patient and carer involvement in research.

No matter how complicated the research, or how brilliant the researcher, patients and the public always offer unique, invaluable insights. Their advice when designing, implementing and evaluating research invariably makes studies more effective, more credible and often more cost effective.

Professor Dame Sally Davies
Director General of Research and Development
Department of Health

3. Ambition & Context

Improving Patient Experience

“Patient benefit is top of the pile”. This phrase was repeatedly stated during the dialogue days and is a reminder of the ambition to improve patient experience is the central goal. This may be described through outcome targets measured as living longer or better, less invasive or burdensome treatments to improved care and quality of life. Diagram 1 illustrates the cycle of learning from patient experience as a driver for relevant research, which is then applied to improve services.

The NHS constitution states the ambition that patients should receive information about trials that are relevant and may be of interest. If patients are subsequently to be offered opportunities to participate in these trials then work still remains to increase the number of trials and the research active hospitals, clinics and practices.

The 2010 NHS White Paper ‘Equality and excellence: liberating the NHS’ clearly indicates the importance of developing the link between research and service delivery. The proposed National Commissioning Board will consider relevant research when commissioning services. This provides more opportunities for patients to benefit from the most effective evidence based practice.

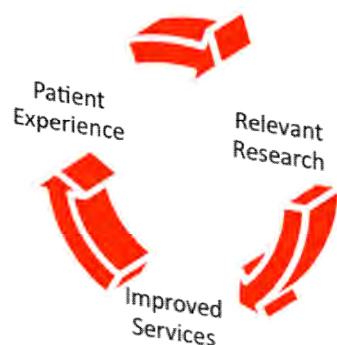


Diagram 1

patients and there are increasing numbers of patients, carers and the public willing to help and get involved contrary to the perception that people would not be interested.

Issues raised of particular interest to patients were about research into rarer forms of illness, the quality of trial information leaflets, consent being truly informed, and how the elements of patient pathways and choice could be integrated with research choice. Currently there are no means of gathering and channelling these issues.

Whether it is people advocating for clinical research to clinicians/nurses through providing powerful stories from their experience, or practically offering advice to help shape a trial in development, public money should have public input.

The National Institute for Health Research (NIHR) has a single clear remit – to improve the health and wealth of the nation through research. NIHR research is firmly focussed on the needs of patients and the public.

These are important ambitions if we are to achieve benefit for

Why isn't it more joined up? IMPROVING RELATIONS

A regional Research Design Service is working with a Comprehensive Local Research Network to build a map of patient & public involvement and other self-help and support groups.

One Stroke Local Research Network has developed links with the local Asian business community to promote the work of the Network and increase knowledge about prevention and research.

Much of the discussion during this dialogue has been about our responsibility to ensure that there is value for health, value for research and value for money.

The Network Context

Almost every contribution to the Way Forward Panel began with statements about how different each Network was from the other. Although these valid differences are key to understanding the context of the Networks there is still much that is similar and generic when involving patients, carers and the public.

National Institute for Health Research (NIHR)

The National Institute for Health Research (NIHR) has a clear remit – to improve the health and wealth of the nation through research. NIHR research is firmly focussed on the needs of patients and the public. It therefore makes sense to include and involve patients, carers and the public to ensure that their needs are understood.

The goals of NIHR include:

- Establish the NHS as an internationally recognised centre of research excellence
- Attract, develop and retain the best research professionals to conduct people-based research.
- Commission research focussed on improving health and social care.
- Strengthen and streamline systems for research management and governance
- Act as sound custodians of public money for the public good.

Each of these goals resonate because the NHS has a special place in the minds of patients, carers and the public in almost every poll and survey carried out in recent years.

It is of value to gain insight from patients/carers and the perspectives of the public when planning, delivering and assessing research. Many patients and carers comment on their whole journey through health and social care rather than just a specific illness, condition or disease. They are keen to remove unnecessary bureaucracy.

The focus for NIHR is NHS England although many of the Clinical Networks include or have affiliations in Scotland, Northern Ireland and Wales.

The Clinical Research Network

The Network Structure is structured as follows:

- Topic or disease specific Clinical Research Network. These six Networks cover Cancer, Mental Health, Diabetes, Neurodegenerative Diseases, Stroke and Medicines for Children. These Networks focus on the development and delivery of a high quality, balanced portfolio of studies that cover a broad range of methodologies and disease areas, working in collaboration with industry and sustaining and increasing accrual into studies.

- The Comprehensive CRN is made up of 25 Comprehensive Local Research Networks (CLRNs) which cover the whole of England by region. These locally based Research Networks coordinate and facilitate the conduct of clinical research and provide a wide range of support to the local research community.
- Primary Care Network brings together a wide range of primary care health professionals and promotes high quality research in areas for which primary care has particular responsibility. These include disease prevention, health promotion, screening and early diagnosis, as well as the management of long-term conditions, such as arthritis and heart disease.
- Clinical Research Network Coordinating Centre (CRN CC) is responsible for managing the overall performance of the Networks. In addition to this, the Coordinating Centre team develops and delivers streamlined central systems (CSP), and undertakes specialist cross-cutting activities to support the commercial life-sciences industry, develop the research workforce, and promote patient and public involvement in clinical trials.

Local Research Networks (LRNs) are an integral part of the Clinical Research Networks yet deserve particular mention at this point. Apart from CCRN & PCRN, support for PPI in the TCRNs has historically often tended to focus on the Coordinating Centres, and the importance of the Local Research Network role in PPI has only more recently begun to be recognised. Resources for Local Research Networks remain challenging but as they are closer to the patients, we should be making more effort to support their work. They are key at a local level especially where there are natural hubs – teaching hospitals, academic units, principal investigators – so why set up separate PPI research groups when we could use existing service (NHS) groups. These Networks are plugged into local events, media and could play an important role with public awareness and involvement. One person felt that there was a lack of respect for LRNs.

The differences included: Mental Health mentioned the challenges of discrimination, Diabetes referred to the large numbers of patients many of whom are as yet undiagnosed, Stroke about involving carers, Medicines for Children referred to parental expectation, Cancer about their link with service delivery and relationship with funders, Dementias about the degenerative nature of the condition, the focus for the Primary Care and Comprehensive Networks on the delivery of trials across a broad spectrum of illness. The Clinical Research Network Coordinating Centre has the significant role of providing the infrastructure, support and pulling together of the network.

These important differences themselves may be summarised as being to do with the patient community, the role of each network and the breadth of their activity.

Patient community: These were categorised as factors relating to an illness, condition or disease; that community's perception and expectation of service delivery and research; and their knowledge and experience of involvement.

Network role: The differences here related to whether the Network helped with the development of trials or focused entirely on adoption and delivery of trials. It appears easier to engage initially with patients around a particular disease and more challenging to show interest across a variety of conditions.

Service delivery: These operational differences included the variety of national coverage, links to clinical delivery and relationships with funders / charities as well as strength of network hubs and infrastructure such as trial units.

Similarities in Involvement

Despite these important contextual differences, the goal of patient benefit remains the same, as does much of the task of involving people in activities on the continuum from consultation through to partnership.

There is a need to recognise the different worlds and also to recognise areas where they can be joined together. We must however appreciate that some population specific approaches are not necessarily transferable to another disease area.

A number of contributions remarked on the need to encourage the PPI leads to work collaboratively to avoid repetition and duplication of effort. One spoke of a logic to have one PPI service across all networks and others of the need to link up with other activities in 'whole systems' model, creating greater efficiencies.

There was no desire for a 'top down' model for involvement, which might stifle innovation and far more support for a framework of involvement built in a collaborative effort to develop buy in from the various Networks. There was also concern about how local Hubs might take on roles for the whole network to avoid repetition /duplication.

The importance and value of other organisations was noted and their participation in this process greatly appreciated. INVOLVE (www.invo.org.uk) the national advisory group funded by the Department of Health are the focal hub of patient and public involvement in research and provide extremely helpful support and publications. The Research Design Service (www.nihr.ac.uk) is in a unique position to influence the thinking about trial design with the involvement of patients, carers and the public. The Research Ethics Service (www.nres.npsa.nhs.uk) similarly is keen to see trials that are safe and that are well designed. The James Lind Alliance (www.lindalliance.org) has recently published guidance on setting up Priority Setting Partnerships, providing a systematic approach to identifying treatment uncertainties that involves both patients and clinicians.

It was similarly suggested that we should do more joined up work with the NIHR Biomedical Research Centres and Units (BRCs and BRUs) as well as the Collaborations for Leadership in Applied Health Research and Care (CLAHRCs). The Way Forward process has strengthened existing relationships and helped create new ones that will be developed further. The role of the Networks in involving patients, carers and public should not be seen in isolation from other research organisations doing the same. The

What is a lay reviewer?

IMPROVING UNDERSTANDING OF RESEARCH

Many people have little understanding of research and trials. This example shows how it is possible to explain some elements of the research process.

Young people spent an evening exploring what it is like to be a lay reviewer. As members of the Medicines for Children Research Network - Advisory Group they were interested in the amount of work that goes into what young person has saw as 'just giving me a pill on a trial'.

The Way Forward

Making a difference in research by actively involving people

following model used at an early stage and found helpful in the Way Forward process sees this in terms of the research pathway from the first idea through to completion in terms of the organisations involved:

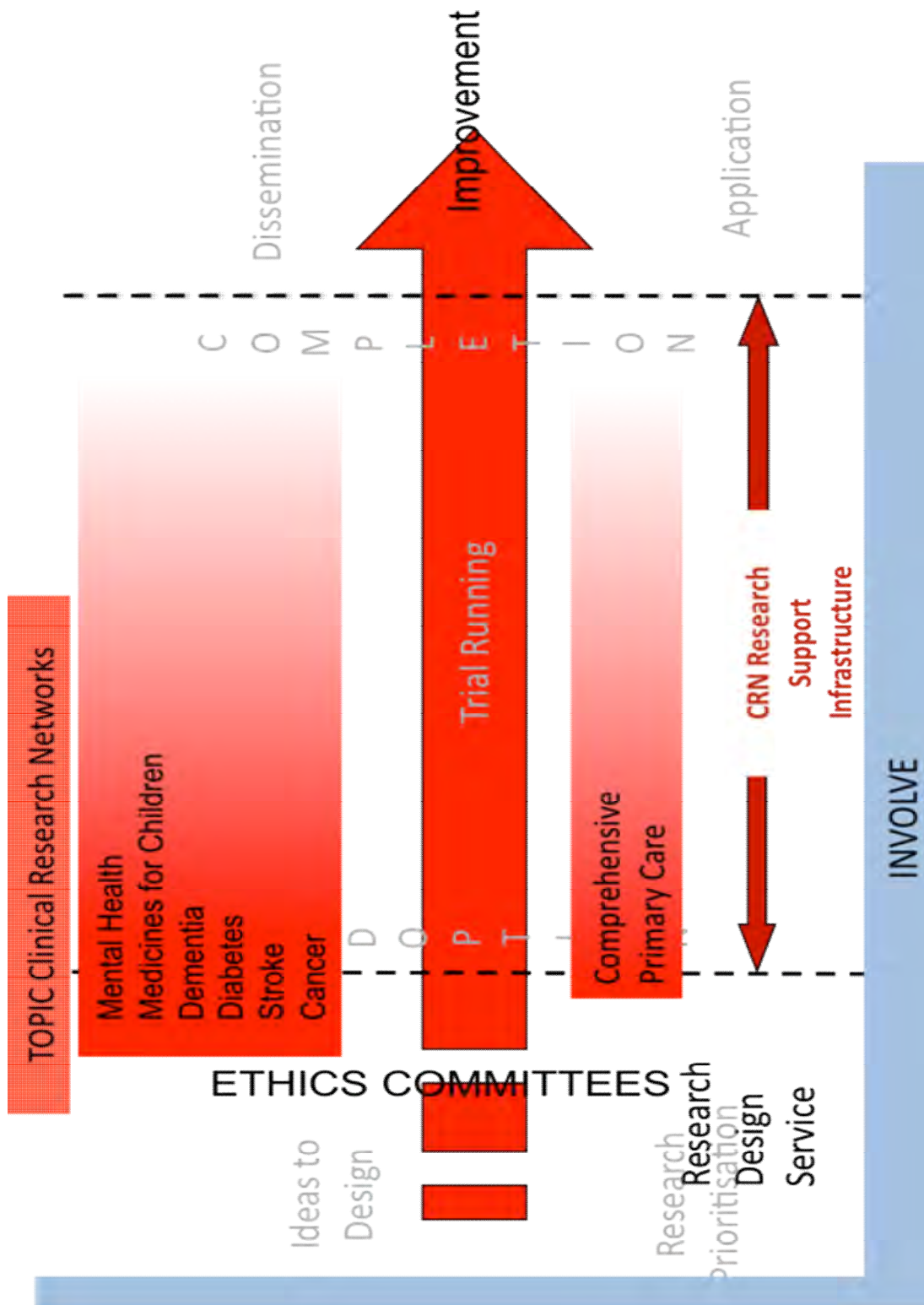


Diagram 2 This arrow diagram originated by Roger Steel illustrates the key linear stages of the research process to allow people to map different organisations and the show some of the various elements of the Network

4. Rationale and focus

Why are we actively involving people?

Almost all research has a direct or indirect benefit on future patient care.

Nowadays, more people want to know about research that is taking place particularly when it directly affects them either as a patient, carer, family or friend. Such enquiries regarding research opportunities have increased with the availability of the Internet. It is likely to increase further with the continued developments in modern technologies. The progress in personalised medicines and care may add to further interest. The establishment of the National Institute for Health Research Clinical Research Network (NIHR CRN) has provided a vision, improved the coordination and developed an infrastructure to lessen the time taken to get trials up and running and to increase the numbers of people participating in trials.

We have opened the doors to research through the active involvement of patients, carers and the public. There has been a steady, year on year, increase in the numbers of people becoming actively involved and in the breadth of activity and differing roles.

Patients are providing insight from their own personal experience. Carers are adding their viewpoint on helping a patient through a journey. The public are offering an external perspective of their expectations of research and health services.

We need to recognise that each of these voices is different. As a result we become clearer about what can be achieved through involving people making best use of our effort and time.

We will...

- Focus more on why we are involving people and what is expected if we are to maximise the value for research, patient health and money.
- Promote equity and diversity to ensure that the activities we establish do not further exclude those who are likely to be hard to reach.

Can I take part in a trial?

IMPROVING ACCESS

Although there is an increasing interest in research often when someone does find out about a specific study, which might or might not be suitable for them, they may be unable to be offered the choice if their Doctor or Consultant is not involved in the trial.

One person who was invited to get involved with research came across information about a clinical trial, being run by the Primary Care Research Network. This individual took the information to her own doctor's surgery and they are now taking an active role in research.

This simple illustration shows how involving patients can help improve access, albeit in one surgery, yet the NHS Constitution states that patients should be given information about relevant research.

What is the Value for Research?

Will I understand?

IMPROVING COMMUNICATION

Significant improvements have taken place in doctor patient communications but for certain groups it still remains challenging.

Carers of people with dementia, from the Dementia and Neuro-degenerative Diseases Network, ran a workshop for clinicians to help them understand what it is like for these patients and carers to be recruited on to a trial.

This example demonstrates how professionals can learn directly from patient experiences.

In almost every sphere of commercial and retail business, the customer is viewed as the most important person. It is virtually inconceivable in those settings that you wouldn't want to hear and act upon the views of those who are going to buy and potentially benefit from a product or service. Customer focus, care and satisfaction are equally important drivers in cooperatives and non-profit making environments.

Accordingly, it makes sense in research to involve people with direct patient experience, carers and members of the public who can each provide unique insights. The earlier that involvement takes place in the research process the more likely the benefit. For those of us who get involved, it can be rewarding for our understanding and knowledge of the challenges and complexity of research. It can be equally frustrating to witness the duplication of effort, the delay and unnecessary barriers.

We will...

- Define and target effective involvement in the context of Networks
- Focus involvement where it creates the maximum impact

What is the Value for Patient Health?

Patients and the public should have confidence knowing that the treatment and care they receive is based on the best evidence especially as the National Health Service is held in high regard and valued by the population.

Research that is relevant to patients' needs and is directly pertinent to their quality of care is more likely to be acceptable to patients and potentially recruit participants. There is an increasing view that clinical settings which are actively involved in research

Do I know about research?

IMPROVING AWARENESS

Too often we wait until after a person is diagnosed with an illness before we even speak about research. The Diabetes Clinical Research Network arranged for a stand at a community event.

The East London Mela attracts thousands of people. The Diabetes Research Network arranged to have a stand through the links created by a lay panel member. Blood glucose tests were offered and over 500 questionnaires were completed.

Such involvement helps to raise awareness amongst this 'at risk' group and gathered views about needs.

may be providing better treatments and care for all their patients.

Consequently placing the patient at the centre is not just a reminder of purpose but can be a lever for service improvement.

For patients who become involved there is good evidence that that the more they understand health matters the better their own health. It can at times be difficult to ensure that research is applied into service delivery.

We will...

- Increase the ways in which we gather patient experience
- Promote the value for patient health as a lever for change

What is Value for Money?

Trials that fail to recruit for whatever reason are a waste of money. This may be because some are proposed to recruit in an inappropriate setting for patients, have poor information sheets, make too many demands or have a burden that is too great for the participant.

In stringent times it is even more important to ensure that planning for research takes the patient perspective into account. Much of the funding in research is public money collected through taxation or from charitable donation. People have climbed mountains, helped in a charity shops or rattled a tin to raise money.

For those who become involved we want to see how money spent wisely.

We will...

- Work closely with related organisations to improve the quality of research proposals
- Create a series of dialogues on matters of importance to patients

Am I interested in taking part?

IMPROVING RECRUITMENT

Information that is appropriate and meaningful is more likely to help informed consent.

Recruitment rose from 18% to 38% for a trial a Mental Health Research Network after bringing together a number of service users to redesign the recruitment leaflet to make it more relevant.

Trials that fail to recruit effectively can be a waste of public funds.

5. The Five Strands of Practice

Early on in the process the Way Forward Panel identified 5 distinct strands to the business of involving patients, carers and the public that offered a means of categorising the information collected from the dialogues and providing focus. These were:

- **Principles & Values**
- **Purpose, Impact & Benefit**
- **Encouraging & Sharing Good Practice**
- **Sustainability**
- **Structures, Systems & Processes**

We have arranged much of the collected information from the Way Forward dialogues into these levels in a separate document. However, the actions to emerge as a result of these dialogues are summarised here under the five strands. The actions are likely to form the basis for a Framework for the Clinical Research Networks, which will outline how these might be applied in a daily context.

Principles and Values

To improve the Principles & Values there is a need to:

- Show a clear relationship between the involvement activity and its long-term value for patients
- Develop a common understanding of the overall purpose of involving people in each organisation
- Show a clear relationship between the involvement activity and its value to the core Network objective
- Clarify expected value and outcomes of any involvement activity
- Adopt Network wide minimum standards for working relations between research professionals and involved patients and public
- Show a clear relationship between these activities and accountability to the public

Purpose Impact and Benefit

To improve Purpose, Impact & Benefit we need to...

- Record the desired value and intended outcome of involvement activity before commencing
- Regularly review PPI activity for continued learning, development and evaluation (e.g. annually and by project)
- Collect PPI review outcomes
- Work to improve quality and relevance of NIHR Portfolio studies to patients and public.
- Improve quality and speed of research and study success

- Identify links between PPI strategy and wider Department of Health policy relating to patient benefit. E.g. NHS Constitution and NHS Operating Framework
- Work to improve research culture for more openness and inclusion
- Identify links between PPI activity and improved patient journeys for research participants
- Make links between PPI activity and improved communication and information to potential and actual research participants

Encouraging, learning and sharing good practice

To improve Sharing of good practice there is a need to:

- Share experience of what has been learnt and disseminating success stories (E.g. examples and case studies)
- Collaborate on ways of working between networks and with external stakeholders both at a local (LRN) level as well as national (CRN) level.
- Collaborate on ways of working between networks and with external stakeholders both at a local (LRN) level as well as national (CRN) level.
- Develop a PPI communications strategy in each Network
- Routinely inform people about opportunities to get involved (e.g. local and national events)
- Increasingly integrate PPI with other work areas within each Network organisation (e.g. training and communications)

Sustainability

To improve Sustainability we need to...

- Pool expertise and resources at a national level
- Pool expertise, and resources across research organisations at a local level where possible
- Plan resourcing to fulfil the PPI activities with most impact
- Review balance of PPI resourcing between coordinating centres and Local Research Networks (or Hubs)
- Continued support available to enable involvement
- Employ staff with appropriate skills and knowledge at Coordinating Centres.
- Build capacity and recruitment
- Develop a system of succession planning for replacing PPI stakeholders who complete a term of office

Structures, Systems and Processes.

To improve Structures, Systems and Processes we need to:

- Agree a collaborative framework for PPI between the different Networks, and develop and maintain systems / forums to support greater collaboration

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-
- Clarify roles and responsibilities between Networks and Centre.
 - Engage with and commit resources to agreed areas of collaboration
 - Consider communication & access
 - Develop a coherent training, learning and support network for involved patients, carers, public and research professionals
 - Employ staff with appropriate skills and knowledge at Coordinating Centres

6. Conclusion

We believe that the actions and rationale in this report are an important landmark in the development of involving patients, carers and the public despite the focus on the particular context of the Clinical Research Networks. These are the proposals submitted to the Department of Health and will form the basis of the business plan.

It was not possible to include all the deliberations of the Way Forward dialogues in this short report. However, a rich collection of information from the dialogues is available in a further document available separately. We urge you to read this as we think it will be a very useful to guide to the next phase.

We will now embark on the implementation of change using what we have found works best so far in this process – that of dialogue, decision and action. There is much to be achieved over the next year and more, yet we intend that the process will be conducted through consensual, collective and lived leadership rather than imposed like a policy. The nature of the dialogues so far has indicated that people appreciate being involved in developments that will affect them. This applies equally to this process as it does to many other aspects of life. After all, this is one of the main reasons we want to have patients, carers and the public involved in research in the first place.

We can therefore look forward to a dynamic time ahead where innovation will be just as important as continuity.

7. Acknowledgements

Thank you to everyone who has contributed from across the Network, from other organisations and from patients to directors. Thank you to all the members of the Panel who gave up two days to listen, learn and reflect on the dialogue.

Particular thanks are due to Roger Steel who has led, cajoled and brought together much of the process. Endless thanks are also due to Sam Taylor, Ann Johnson, Pat Hill and Sarah Fenn who organised, coordinated and put up with this venture.

A list of contributors is available in Appendix 2.

8. Appendix 1

PPI The Way Forward – Glossary

| | |
|----------------|---|
| AMRC | The Association of Medical Research Charities |
| CC | Coordinating Centre |
| CCF | Central Commissioning Facility |
| CCRN | Comprehensive Clinical Research Network |
| CRN | Clinical Research Network |
| CLRN | Comprehensive Local Research Network |
| CTRU | Clinical Trials Research Unit |
| DeNDRoN | Dementias and Neurodegenerative Disease Research Network |
| DRN | Diabetes Research Network |
| DH | Department of Health |
| GCP | Good Clinical Practice |
| GP | General Practitioner |
| LRNs | Local Research Networks |
| MCRN | Medicines for Children Research Network |
| MHRN | Mental Health Research Network |
| MRC | Medical Research Council |
| NCRN | National Cancer Research Network |
| NETSCC | The NIHR Evaluation, Trials and Studies Coordinating Centre |
| NIHR | National Institute for Health Research |
| NHS | National Health Service |
| NRES | National Research Ethics Service |
| PCPI | Patient, Carer and Carer Involvement |

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| | |
|-------------|--|
| PCRN | Primary Care Research Network |
| PPI | Patient and Public Involvement |
| RDS | (NIHR) Research Design Service |
| SRN | Stroke Research Network |
| TCRN | Topic Specific Clinical Research Network |
| UoL | University of Leeds |

9. Appendix 2

PPI The Way Forward Contributors

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Consultation Process 13th August – 3rd September 2010

Aim

This consultation survey aimed to build on the dialogue started during face to face meetings with wide range of stakeholders in London during May 2010, and enable a broader range of people to contribute to this process by sharing their views. The survey focused on some of the practical aspects of delivering PPI for maximum impact in the Clinical Research Networks over the next five years.

Who was invited to take part?

- Clinical and non-clinical professionals associated with the NIHR Clinical Research Networks
- Service users/lay people/patients/carers associated with the Clinical Research Networks
- Professionals associated with organisations outside the Clinical Research Networks but who work with the Networks.

Outcome

The consultation process survey was anonymous but we received completed responses from 193 people.

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